REMARKS

Claims 1 – 105 are cancelled in the present Amendment and Request for Continued Examination after Board Decision of July 25, 2006. These cancellations are made without acquiescing to the Examiner's or the Board's rejection, but are made to further prosecution and the Applicant's business interests. The Applicant reserves the right to prosecute Claims 1-105 (or similar claims) in the future. Claims 106 - 191 are added with the present amendment. Therefore Claims 106 - 191 are currently pending.

In the Board Decision of July 25, 2006 the Board has affirmed the Examiner's rejection of the claims as obvious. For example, the Board states:

> "The Examiner has made out a prima facie case of obviousness, which Appellant has not effectively rebutted. The examiner's rejection is supported by a preponderance of the evidence in the record and is therefore affirmed." (Board Decision of July 25, 2006, page 18).

The Board has fallen into the same error as the Examiner in concluding that a *prima facie* case of obviousness has been established. To the contrary, neither the Board nor the Examiner has ever put forward any evidence whatsoever of a motivation to combine the references cited by the Examiner. The only statement the Board is able to make with regard to a motivation in the record to combine the Examiner's references consists of the assertion:

> "In this case, a person of ordinary skill in the art would have found it obvious, in view of the cited references, to test a patient for genetic markers in order to avoid known surgery- and anesthesia-related complications, even though such tests might be expensive, because those skilled in the art would have recognized that the tests were useful for diagnosing patients who were likely to suffer complications if given certain drugs." (Board Decision of July 25, 2006, page 14).

The Board has made several errors. First, the perioperative genomic profiles of the present invention are not confined to tests "useful for diagnosing patients who were likely to suffer complications if given certain drugs." To the contrary, the perioperative genomic profiles of the present invention combine genetic markers of pharmacogenetic risk with, for example, genetic markers of co-existing symptomatic conditions, genetic markers of co-existing non-symptomatic conditions, genetic markers of outcomes of a surgical procedure, genetic markers of a patient in a specific group, genetic markers that predict postoperative outcomes, and genetic markers consisting of unique genomic identifiers. Neither the Examiner nor the Board has ever indicated where a teaching or suggestion to make these combinations is to be located in the prior art. Clearly, such a motivation is nowhere to be found in the Examiner's references of record.

Second, the Applicant points out that the Board's *post hoc* recognition of the usefulness of the invention in hindsight (that is, in possession of the invention) is not evidence of motivation to combine references, and cannot be substituted for factual evidence of a motivation, teaching or suggestion to make the combination of the Examiner's references. That an invention is recognized as useful by the Examiner and the Board after it has been made does not render the invention obvious, although this is the express assertion of both the Examiner and the Board. To prevent the Examiner and the Board from falling into this trap, the Patent and Trademark Office and CAFC require that factual evidence of a motivation to make the Examiner's combination of references be provided.

If such evidence exists that the ordinary artisan (*e.g.*, a clinician) would have found the perioperative genomic profiles of the present invention obvious at the time the invention was made, why have the Examiner and Board never provided such evidence? It is not sufficient that the Board and Examiner (*i.e.*, not clinicians of ordinary skill in the art) regard the invention as obvious while in possession of the invention itself. Nor is it sufficient for the Board and the Examiner to speculate what a clinician of ordinary skill would or would not have recognized. Rather the Patent and Trademark Office's burden is to make the determination of obviousness as a factual matter, with facts based on evidence of record, not conclusory speculation on the part of those with the blueprint for the invention in their hands.

To the contrary, the Applicant has provided factual evidence that the Patent and Trademark Office has never met its duty to establish a *prima facie* case of obviousness in the first instance. For example, the Second Declaration of Kirk Hogan, M.D. under 37 C.F.R. §1.132 states:

> "The ordinary artisan did not clearly recognize the benefit of testing an individual prior to surgery and subjection to anesthesia for known genetic markers associated with conditions triggered by anesthesia or surgery at the time the invention was made." (Second Declaration of Kirk Hogan, M.D., page 2.)

Neither the Examiner nor the Board has ever provided evidence contradicting this evidential declaration of fact. Indeed, in its Decision of July 25, 2006 the Board has failed to address, or even mention, this statement of fact. If the Examiner and Board have evidence to the contrary it should be cited.

The Applicant points out to the Examiner that the perioperative genomic profiles of the present invention are a solution to the problem of detecting genetic variation in patients undergoing anesthesia and surgery, and that all available evidence indicates that this solution was not obvious to the artisan of ordinary skill at the time the invention was made. The perioperative genomic profiles of the present invention exhibit a particularly advantageous technical effect that provides a perioperative treatment course of action that is specific for each patient, regardless of whether the positive and negative results of the perioperative genomic profile are or are not shared between patients. None of the Examiner's references, alone or in combination, teach or suggest methods for selection of genes and alleles for inclusion on the perioperative genomic profiles of the present invention. None of the Examiner's references, alone or in combination, teach or suggest a perioperative treatment course of action based on the results of the perioperative genomic profile of the present invention.

The Applicant points out to the Examiner that both the Examiner and the Board have failed to consider the obviousness of former claim 101 (similar to new claim 143) except as a pooled rejection of many claims. The Examiner has improperly used Quane as a motivation to make the Examiner's combinations to reject former claim 101. Hence,

even if Quane were permissible as a reference for this purpose, and it is not, Quane has no bearing on the patentability of former claim 101, or new claim 143 standing alone.

The Applicant observes that both the Board and the Examiner confuse a clinician of ordinary skill in the practice of the present invention, *i.e.*, a clinician skilled in the delivery of a perioperative treatment course of action, with an artisan of the Examiner's improper choice *i.e.*, a molecular biologist unskilled in clinical medicine and perioperative care. This confusion has contributed to the Examiner's and the Board's failure to establish a *prima facie* case of obviousness, failure to examine former claim 101, and failure to provide factual evidence of a motivation to combine the Examiner's references. The Examiner and the Board have never provided evidence teaching or suggesting how to provide the perioperative genomic profiles of the present invention to provide a perioperative treatment course of action in the absence of the disclosure of the present invention. The prior art of record must be viewed from the perspective of the skilled artisan. Any rejection of the claims must provide evidence that the appropriate skilled artisan would find the invention obvious. Presently, the Office has not viewed the invention from the perspective of the correct skilled artisan, and there is no evidence in the record suggesting obviousness so as to create a *prima facie* showing. The only evidence in the record from the correct perspective (Hogan Declaration II, *vide supra*) evidences non-obviousness

While the Applicant believes that the prior claims are patentable for at least the above reasons of record, the Applicant has cancelled the pending claims and added new claims. In the present Amendment and Response to Board Decision of July 25, 2006 the Applicant has cancelled claims 1 –105, and added claims 106 – 191. The Applicant notes that the Examiner's references are missing one or more elements of the new claims, and that all elements are found in the Specification. In turn, the Applicant notes that the Examiner's references fail to provide a teaching, motivation or suggestion to combine the Examiner's references, and thereby arrive at the perioperative genomic profiles of the present invention.

The cancellation and addition of claims presented herein are made without acquiescing to any of the Examiner's or Board's arguments or rejections. The addition of claims presented herein are made solely for the purpose of expediting the patent

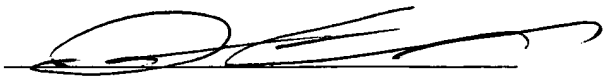
application process in a manner consistent with the U.S. Patent and Trademark Office's Patent and Business Goals (PBG),[1] and without waiving the right to prosecute the cancelled claims (or similar claims) in the future.

[1] 65 Fed. Reg. 54603 (Sept. 8, 2000).

CONCLUSION

The Applicant believes that the pending claims should be passed into allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

Dated: 9/25/06



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